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EXAMINER	
CARLSON, KAREN C	
ART UNIT	PAPER NUMBER
1656	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/593,958	BORGFORD ET AL.	
	Examiner	Art Unit	
	KAREN CARLSON	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *March 16, 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 29-46* is/are pending in the application.

4a) Of the above claim(s) *9-18, 29-32, 34, and new Claims 37-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,33,35 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's election without traverse of Group 1, Claims 1-8, 33, 35, and 36, in the reply filed on March 16, 2011 is acknowledged.

Claims 19-28 have been cancelled. The Examiner has withdrawn Claims 9-18, 29-32, 34, and new Claims 37-46 from further consideration because these claims are drawn to non-elected inventions. Claims 1-8, 33, 35, and 36 are currently under examination.

Benefit of priority is to March 24, 2004.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See page 27 of the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 33, 35, and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is drawn to non-mutated A and B chains, yet Claims 2-8 broaden Claim 1 by referring to mutations within the protein of Claim 1 or by claiming fragments and

analogs of Claim 1. Thus, while Claim 1 appears to be clear as written, the limitations of Claim 1 cannot be ascertained in view of the limitations of the dependent claims.

Additionally, Claims 6-8 should refer to "SEQ ID NO:", not ---SEQ ID No.—in accordance to the sequence rules 37 CFR 1,821 and that no claim shall comprise more than a single period at the end of the claim.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 5-8, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Borgford (1997; WO 97/41233).

Borgford teaches fusion proteins comprising the A chain of a ricin-like toxin, a B chain of a ricin-like toxin, and a heterologous linker linking the A and B chains, wherein the heterologous linker contains a cleavage recognition site for HIV or an HTLV protease, which is are disease specific proteases (see abstract, for example; **Claim 1**). Proricin comprising the fusion protein and the ricin secretion signal sequences was isolated (page 27, lines 8+; **Claim 5**). Pharmaceutical compositions of the fusion protein is discusses at page 22, line 24-page 23, line 30 (**Claim 33**).

Instant SEQ ID NO: 1, NO: 2, and NO: 3 are amino acid sequences depicting fusion proteins comprising the A chain of ricin, the B chain of ricin, and a heterologous linker comprising an MMP9 cleavage site. Therefore, the fusion protein of Borgford comprises a fragment of or is an analog of SEQ ID NO: 1 (**Claim 6**), SEQ ID NO: 2 (**Claim 7**), and SEQ ID NO: 3 (**Claim 8**).

Claims 1, 5-8, and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Borgford. (USP 6,803,358, issued October 12, 2004 and having priority to at least April 14, 2000).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Borgford teaches fusion proteins comprising the A chain of a ricin-like toxin, a B chain of a ricin-like toxin, and a heterologous linker linking the A and B chains, wherein the heterologous linker contains a cleavage recognition site for specific proteases found in inflammatory cells and cancer cells (**Claim 1**). The cleavage site can be for MMP9 (SPQGIAGQRNFN; Col. 7, line 26). Proricin comprising the fusion protein and the ricin secretion signal sequences was isolated (Col. 38, Example 2; **Claim 5**). Pharmaceutical compositions of the fusion protein is discusses at Col. 34, line 31 to Col. 35, line 25 (**Claim 33**).

Instant SEQ ID NO: 1, NO: 2, and NO: 3 are amino acid sequences depicting fusion proteins comprising the A chain of ricin, the B chain of ricin, and a heterologous linker comprising an MMP9 cleavage site. Therefore, the fusion protein of Borgford comprises a fragment of or is an analog of SEQ ID NO: 1 (**Claim 6**), SEQ ID NO: 2 (**Claim 7**), and SEQ ID NO: 3 (**Claim 8**).

Claims 1, 5-8, and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Braun et al. (USP 7,060,789, issued June 13, 2006 and having priority to at least October 4, 2000).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Braun et al. teach fusion proteins comprising the A chain of a ricin-like toxin, a B chain of a ricin-like toxin, and a heterologous linker linking the A and B chains, wherein the heterologous linker contains a cleavage recognition site for specific proteases found in inflammatory cells and cancer cells (**Claim 1**). The cleavage site can be for MMP9 (Col. 6, line 47). Proricin comprising the fusion protein and the ricin secretion signal sequences was isolated (Col. 25, Example 2; **Claim 5**). Pharmaceutical compositions of the fusion protein is discusses at Col. 22, line 45-Col.23, line 26 (**Claim 33**).

Instant SEQ ID NO: 1, NO: 2, and NO: 3 are amino acid sequences depicting fusion proteins comprising the A chain of ricin, the B chain of ricin, and a heterologous linker comprising an MMP9 cleavage site. Therefore, the fusion protein of Braun et al. comprises a fragment of or is an analog of SEQ ID NO: 1 (**Claim 6**), SEQ ID NO: 2 (**Claim 7**), and SEQ ID NO: 3 (**Claim 8**).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Borgford (1997; WO 97/41233) and Wales et al. (1991;

Mutational analysis of the galactose binding ability of recombinant ricin B chain. J. Biol. Chem. 266(29): 19172-19179).

The teachings of Borgford are set forth above (**Claim 1**). Borgford does not teach to mutate glycosylation sites in the ricin B chain.

Wales et al. show that mutation of one or both glycosylation sites in the B chain results in a soluble and stable ricin B chain having reduced lectin activity. At page 19178, the para bridging the columns, Wales et al. point out that the B chain ensures potent cytotoxicity of intact ricin immunotoxins, but it overrides the specificity conferred by the antibody. Thus, mutant galactose binding-deficient B chains may be a valuable component of intact ricin immunotoxins.

It would have been obvious for a person having ordinary skill in the art to mutate the ricin fusion protein of Borgford by reducing the glycosylation sites in the B chain (**Claims 2-4**) because Wales et al. teach that the substitution of glycosylation sites in the B chain reduces/eliminates the lectin/cell binding activity of the B chain and this may be valuable in preventing the B chain from attaching to non-cancerous cells, that is, in the example provided in Wales et al., overriding the specificity of the antibody component of ricin immunotoxins. Thus, reduced lectin/cell binding activity of the mutated ricin B chain would prevent the ricin fusion protein of Borgford from binding to non-target, non-cancer cells that do not provide the disease specific protease to cleave the ricin fusion protein of Borgford, thus reducing the systemic toxicity of the fusion protein while enhancing the toxicity of the ricin at the cancer cells.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Borgford (USP 6,803,358) and Wales et al. (1991; Mutational analysis of the galactose binding ability of recombinant ricin B chain. J. Biol. Chem. 266(29): 19172-19179).

The teachings of Borgford are set forth above (**Claim 1**). Borgford does not teach to mutate glycosylation sites in the ricin B chain.

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It would have been obvious for a person having ordinary skill in the art to mutate the ricin fusion protein of Borgford by reducing the glycosylation sites in the B chain (**Claims 2-4**) because Wales et al. teach that the substitution of glycosylation sites in the B chain reduces/eliminates the lectin/cell binding activity of the B chain and this may be valuable in preventing the B chain from attaching to non-cancerous cells, that is, in the example provided in Wales et al., overriding the specificity of the antibody component of ricin immunotoxins. Thus, reduced lectin/cell binding activity of the mutated ricin B chain would prevent the ricin fusion protein of Borgford from binding to non-target, non-cancer cells that do not provide the disease specific protease to cleave

the ricin fusion protein of Borgford, thus reducing the systemic toxicity of the fusion protein while enhancing the toxicity of the ricin at the cancer cells.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Braun et al. (USP 7,060,789) and Wales et al. (1991; Mutational analysis of the galactose binding ability of recombinant ricin B chain. J. Biol. Chem. 266(29): 19172-19179).

The teachings of Borgford are set forth above (**Claim 1**). Borgford does not teach to mutate glycosylation sites in the ricin B chain.

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It would have been obvious for a person having ordinary skill in the art to mutate the ricin fusion protein of Braun et al. by reducing the glycosylation sites in the B chain (**Claims 2-4**) because Wales et al. teach that the substitution of glycosylation sites in the B chain reduces/eliminates the lectin/cell binding activity of the B chain and this may be valuable in preventing the B chain from attaching to non-cancerous cells, that is, in the example provided in Wales et al., overriding the specificity of the antibody component of ricin immunotoxins. Thus, reduced lectin/cell binding activity of the

mutated ricin B chain would prevent the ricin fusion protein of Braun et al. from binding to non-target, non-cancer cells that do not provide the disease specific protease to cleave the ricin fusion protein of Braun et al., thus reducing the systemic toxicity of the fusion protein while enhancing the toxicity of the ricin at the cancer cells.

Claims 1, 33, 35, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Borgford (1997; WO 97/41233) and Fukuda et al. (1999; Combination therapy for advanced breast cancer: Cyclophosphamide, doxorubicin, UFT, and tamoxifen. Oncology 7(Suppl 3): 77-81; abstract only provided).

The teachings of Borgford are set forth above (**Claim 1, 33**). Borgford also teaches that the fusion protein s useful for treating cancer cells comprising an HTLV protease (page 5, line 36; page 19, line 22, 27; page 23, line 27) and specifically teach to inhibit tumor growth *in vivo* in human breast cancer (page 38, line 15+). Borgford does not teach to make pharmaceutical compositions comprising the fusion protein with additional anticancer agents such as doxorubicin, cyclophosphamide, or 5-flurorouracil.

Fukuda et al. teach that the combination therapy of cyclophosphamide, doxirbicin, and UTF (comprising 5-flurorouracil) and tamoxifen for advanced and recurrent breast cancer produced high response rates and mild adverse reactions and is therefore useful for the treatment of advanced and recurrent breast cancer.

It would have been obvious to a person having ordinary skill in the art to combine the ricin fusion protein of Borgford and the all or any one of the anti-breast cancer drugs

cyclophosphamide, doxorubicin, and 5-flurorouracil used in Fukuda et al. to treat breast cancer because Borgford teaches that the ricin fusion proteins is useful in the treatment of breast cancer and Fukuda et al. teach that the combination of cyclophosphamide, doxorubicin, and 5-flurorouracil produced high response rates and mild adverse reactions and is therefore useful for the treatment of breast cancer (**Claim 35, 36**).

Claims 1, 33, 35, and 36 rejected under 35 U.S.C. 103(a) as being obvious over the combined teachings of Borgford (USP 6,803,358) and Newlands et al. (1997; Temozolomide: a review of its discovery, chemical properties, pre-clinical development, and clinical trials. Cancer Treatment Reviews 23:35-61).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing

that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The teachings of Borgford are set forth above (**Claim 1, 33**). Borgford also teaches that the fusion proteins are useful for treating melanoma (Col. 35, line 33). Borgford does not teach to make pharmaceutical compositions comprising the fusion protein with additional anticancer agents such as temozolomide.

Newlands et al. teach that temozolomide is useful for the treatment of melanoma see entire review and especially page 55, Future prospects).

It would have been obvious to a person having ordinary skill in the art to combine the ricin fusion protein of Borgford and the temozolomide taught in Newlands et al. to treat melanoma because Borgford teaches that the ricin fusion proteins are useful in the treatment of melanoma and Newlands et al. teach temozolomide is useful for the treatment of melanoma (**Claim 35, 36**).

Claims 1, 33, 35, and 36 rejected under 35 U.S.C. 103(a) as being obvious over the combined teachings of Braun et al. (USP 7,060,789) and Newlands et al. (1997; Temozolomide: a review of its discovery, chemical properties, pre-clinical development, and clinical trials. Cancer Treatment Reviews 23:35-61).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The teachings of Braun et al. are set forth above (**Claim 1, 33**). Braun et al. also teach that the fusion proteins are useful for treating melanoma (Col. 23, line 31). Braun et al. do not teach to make pharmaceutical compositions comprising the fusion protein with additional anticancer agents such as temozolomide.

Newlands et al. teach that temozolomide is useful for the treatment of melanoma see entire review and especially page 55, Future prospects).

It would have been obvious to a person having ordinary skill in the art to combine the ricin fusion protein of Braun et al. and the temozolomide taught in Newlands et al. to treat melanoma because Braun et al. teach that the ricin fusion proteins are useful in the treatment of melanoma and Newlands et al. teach temozolomide is useful for the treatment of melanoma (**Claim 35, 36**).

The rejections under 35 USC 103 above are consistent with case law. Applicants are referred to *In re Kerkoven* (205 USPQ 1069) in which it was shown to be *prima facia* obvious to combine two compositions, each of which is taught by the prior art to be used for that very same purpose. *Ex Parte Quadranti* (25 USPQ2d 1071) also sets forth this precedent, in that the use of materials in combination, each of which is known to function for the intended purpose, is generally held to be *prima facia* obvious. *Ex parte Kucera* (165 USPQ 332) clearly states that synergism has no magical status in rendering otherwise obvious subject matter patentable. Therefore, then, barring unexpected results, one would reasonably expect enhanced, additive, or synergistic activity to be observed by combining the compositions or materials.

Claims 1, 5-8, and 33 are rejected on the ground of nonstatutory double patenting over claims 1-4 of U. S. Patent No. 6,803,358 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: The patented subject matter encompasses the instantly claimed subject matter

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claims 1, 5-8, and 33 are rejected on the ground of nonstatutory double patenting over claims 1-11 of U. S. Patent No. 7,060,789 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: The patented subject matter encompasses the instantly claimed subject matter

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN CARLSON whose telephone number is (571)272-0946. The examiner can normally be reached on 6:00 AM - 4:00 PM, Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen Cochrane Carlson/
Primary Examiner, Art Unit 1656